

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration 1431 Harbor Bay Parkway Alameda, California 94502 Telephone: FAX: (510) 337-6847

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September 3, 2003

Mr. Andy Sneddon Site Manager Evans Vaccine, Limited Gaskill Road Speke Liverpool L24 9GR, United Kingdom

Dear Mr. Sneddon:

We acknowledge receipt of your letter dated June 27, 2003, which responds to the Form FDA 483 issued at the conclusion of the June 2-10, 2003 FDA/Team Biologics inspection of the Evans Vaccines Limited (Evans), Liverpool, United Kingdom facility. The response will be placed in Evans' permanent file, and corrective actions will be reviewed and assessed during the next

Sincerely,

Philip R. Lindeman Compliance Officer ORA/Office of Enforcement Division of Compliance Management Operations